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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,869	05/09/2002	Soren Blirup-Jensen	3276.1003-000	8081
21005	7590	08/24/2005	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			DAVIS, DEBORAH A	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,869

Applicant(s)

BLIRUP-JENSEN ET AL.

Examiner

Deborah A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5-17-04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 21-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 21-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's request to withdraw the Office Action mailed April 20, 2004 is granted. Claims 1-10, 21-22 and 36 were not included in the first Office Action. A preliminary amendment dated December 24, 2001 was entered as a letter of communication; therefore, the examiner did not included in the examination. Only claims 23-35 of the preliminary amendment dated April 1, 2003 were examined. Currently, claims 1-10 and 21-36 are pending and under consideration. Claims 11-20 are cancelled.

Please Note

2. The original claim 1 recites "Buffer for use in Zone electrophoresis and/or immunofixation comprising benzoic acid and/or salt thereof." The set of claims titled "CLAIMS PENDING, AS AMENDED HEREIN" recites "Zone electrophoresis and/or immunofixation buffer comprising benzoic acid and/or a salt thereof. The examiner will consider and examine the original claim 1 as the correct claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-4, 10, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Alter et al (USP#5,753,094).

Claims 1-4 and 10 are drawn to a buffer comprising benzoic acid and/or a salt. Claims 21 and 23 are drawn to a kit for zone electrophoresis. Alter et al anticipates the invention in providing kits and buffers for Capillary Zone Electrophoresis (CZE) analysis that includes gel buffer and benzoic acid (column 3, lines 56-67 and column 4, lines 21-30, column 8, lines 50-64). The benzoic buffer can further comprise of Tris or other compounds (column 3, lines 42-45). Salts of benzoic acid can be sodium salt (column 4, lines 13-19).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5-9 and 24-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alter et al in view of Hicks et al (Laboratory Instrumentation, 3rd addition).

Alter et al teaches compositions for use in electrophoresis procedures that include the use of gel buffers comprising benzoic acid (see abstract, summary and column 6). These electrophoresis procedures can involve Immunofixation Electrophoresis, Capillary Zone Electrophoresis and Immunosubstraction Electrophoresis (column 2, lines 30-40). The clinical samples prepared for electrophoretic analysis can be whole blood, plasma and urine (column 3, lines 50-55). Binding partners to a sample of interest, can be formed by coupling the specific binding partners to a solid support using Sepharose gel (column 7, lines 19-41). Benzoic acid and salts of benzoic acid are used in the electrophoresis buffer at various concentrations (column 4, lines 13-19). Salts of benzoic acid can be sodium salt (column 4, lines 13-19). The benzoic buffer can further comprise of Tris or other compounds (column 3, lines 42-45). A power supply was connected to the electrophoretic apparatus at 9000 volts for 5 minutes to perform electrophoresis (column 10, lines 1-31).

Alter et al does not recites the specific steps in the instant method and is silent with respect to specific concentrations.

However, Hicks et al teaches basic electrophoretic procedures for Immunofixation and Zone Electrophoresis that recite basic steps of drying, staining and

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destaining for detection of monoclonal antibodies and other proteins and running the buffer in the electrophoretic apparatus until complete (see page 161 and 173).

It would have been obvious to one of ordinary skill in the art to combine the teaching of Alter et al with the teaching of Hicks et al laboratory procedures because elctrophoretic techniques are well known in the art and can be adapted to standard protocols as taught by Hicks et al. Further, such electrophoretic methods offer speed in separation of proteins and good resolution of proteins components (see page 173 of Hicks et al). With respect to specific concentrations as recited in claims 31-35, one would vary the optimal concentration of the buffer to achieve maximum resolution of the protein in question. With respect to claims 5-9, wherein the benzoic acid and/or sodium salt is present in various concentrations, this also considered as optimization of the prior art especially since it has long been held to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. At 458, 105 USPQ at 236-237. The "discover of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Voesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

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8. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hicks et al (Laboratory Instrumentation, 3rd addition) in further view of Zuk et al (USP#4,281,061).

The teaching of Hicks et al are set forth above, although the reference recite a general teaching of instructions comprising Zone electrophoresis that include filter paper (blotters) staining solutions, antibodies and templates (page 162, paragraph 2, page 164, paragraph 1, page 165, paragraph 4), the references are silent with respect to utilizing these reagents in a kit format. Although claim 22 make reference to claim 1, the examiner views this claim as an independent kit claim, which is separate from the buffer claimed which is an independent product from the kit.

However, the reference of Zuk et al teaches as a matter of convenience the reagents of an immunoassay can be provided as kits, where the reagents are predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest (column 22, lines 63-66)

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to take the general method of zone electrophoresis taught by Hicks et al and format the reagents into a kit as recited by Zuk because it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. One would be motivated because kits are available in pre-measured amount which eliminates the variability that can occur when performing the assay.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- A. Chen et al (USP#5,228,960) teaches a method and electrolyte buffer in the analysis of samples comprising glycoproteins by CZE (see abstract).
- B. Cheng-Ming et al teaches methodologies for Capillary Electrophoretic Immunosubstraction of samples (USP#5,228,960).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

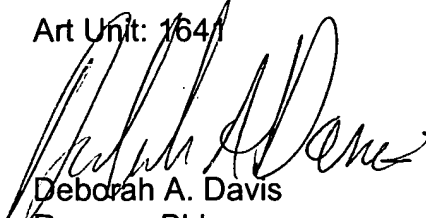
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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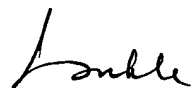


Deborah A. Davis

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Room 3D58

April 15, 2004



LONG V. LE

SUPERVISORY PATENT EXAMINER

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07/25/05